K041239

NOV - 8 2004

510(k) Premarket Notification
Genesis Medical Technologies, Inc.
PharmaJet Needle-free Injector System
Summary of Safety and Effectiveness

10 May 2004

The 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 1992.

Subject:	510(k) Summary of Safety and Effectiveness Information for the Genesis Medical Technologies, Inc. PharmaJet Needle-free Injector System
Submission Correspondent:	Speed To Market, Inc. 1555 East Flamingo Road, Suite 155 Las Vegas, NV 89119 Mr. Thomas Kroenke 303 956 4232 tkroenke@speedtomarket.net
Manufacturer:	Genesis Medical Technologies, Inc. 24797 Foothills Drive North Golden, CO 80401 Ms. Kathleen Callender 303 526 4278 FINNIV@aol.com
Proprietary:	PharmaJet Needle-free Injector System
Common:	Injector, Fluid, Non-Electrically Powered
Classification:	KZE, §880.5430, Class II
Device Description:	The Genesis Medical Technologies, Inc. (GMTI) PharmaJet Needle-free Injector System (PharmaJet System) is a compact, spring-loaded needle-free hypodermic injector system. The PharmaJet System consists of an injector, a cocking station and single-use, sterile, disposable vials.
Intended Use:	The PharmaJet System is intended to deliver various predetermined medicines and vaccines either intramuscularly or subcutaneously by means of a narrow, high velocity fluid jet which penetrates the surface of the skin and delivers the medicine or vaccine to the body.
Test Discussion:	The PharmaJet System was validated through rigorous testing according to international standards and internal protocols to ensure biocompatibility, sterility assurance, functionality, and general device safety.
Test Conclusion:	The PharmaJet System is substantially equivalent to its predicate devices in design concepts, technologies and materials.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 8 2004

Genesis Medical Technologies, Incorporated
C/O Mr. Thomas Kroenke
Principal Consultant
Speed To Market, Incorporated
1555 East Flamingo Road, Suite 155
Las Vegas, Nevada 89119

Re: K041239
Trade/Device Name: Genesis Medical Technologies, Incorporated
PharmaJet Needle-Free Injector
Regulation Number: 880.5430
Regulation Name: Nonelectrically Powered Fluid Injector
Regulatory Class: II
Product Code: KZE
Dated: October 28, 2004
Received: October 29, 2004

Dear Mr. Kroenke:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

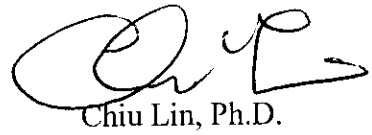
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041239

Device Name: Genesis Medical Technologies, Inc. PharmaJet Needle-free Injector

Indications for Use: The GMTI PharmaJet System is intended to deliver various predetermined medicines and vaccines either intramuscularly or subcutaneously by means of a narrow, high velocity fluid jet which penetrates the surface of the skin and delivers the medicine or vaccine to the body.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K041239